

participants and the presiding officer or the Commissioner referred to in §16.44(c).

(b) The record of the regulatory hearing is closed to the submission of information and views, at the close of the hearing, unless the presiding officer specifically permits additional time for a further submission.

§ 16.85 Examination of administrative record.

Part 20 governs the availability for public disclosure of each document that is a part of the administrative record of a regulatory hearing.

§ 16.95 Administrative decision and record for decision.

(a) With respect to a regulatory hearing at the Commissioner's initiative under §16.1(a), the Commissioner shall consider the administrative record of the hearing specified in §16.80(a) together with all other relevant information and views available to FDA in determining whether regulatory action should be taken and, if so, in what form.

(b) With respect to a regulatory hearing required by the act or a regulation under §16.1(b)—

(1) The administrative record of the hearing specified in §16.80(a) constitutes the exclusive record for decision;

(2) On the basis of the administrative record of the hearing, the Commissioner shall issue a written decision stating the reasons for the Commissioner's administrative action and the basis in the record; and

(3) For purposes of judicial review under §10.45, the record of the administrative proceeding consists of the record of the hearing and the Commissioner's decision.

Subpart F—Reconsideration and Stay

§ 16.119 Reconsideration and stay of action.

After any final administrative action that is the subject of a hearing under this part, any party may petition the Commissioner for reconsideration of any part or all of the decision or action

under §10.33 or may petition for a stay of the decision or action under §10.35.

[44 FR 22367, Apr. 13, 1979, as amended at 54 FR 9037, Mar. 3, 1989]

Subpart G—Judicial Review

§ 16.120 Judicial review.

Section 10.45 governs the availability of judicial review concerning any regulatory action which is the subject of a hearing under this part

PART 17—CIVIL MONEY PENALTIES HEARINGS

Sec.

- 17.1 Scope.
- 17.3 Definitions.
- 17.5 Complaint.
- 17.7 Service of complaint.
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- 17.11 Default upon failure to file an answer.
- 17.13 Notice of hearing.
- 17.15 Parties to the hearing.
- 17.17 Summary decisions.
- 17.18 Interlocutory appeal from ruling of presiding officer.
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- 17.23 Discovery.
- 17.25 Exchange of witness lists, witness statements, and exhibits.
- 17.27 Hearing subpoenas.
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- 17.29 Fees.
- 17.30 Computation of time.
- 17.31 Form, filing, and service of papers.
- 17.32 Motions.
- 17.33 The hearing and burden of proof.
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- 17.35 Sanctions.
- 17.37 Witnesses.
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- 17.41 The administrative record.
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- 17.45 Initial decision.
- 17.47 Appeals.
- 17.48 Harmless error.
- 17.51 Judicial review.
- 17.54 Deposit in the Treasury of the United States.

AUTHORITY: 21 U.S.C. 331, 333, 337, 351, 352, 355, 360, 360c, 360f, 360i, 360j, 371; 42 U.S.C. 262, 263b, 300aa-28; 5 U.S.C. 554, 555, 556, 557.

SOURCE: 60 FR 38626, July 27, 1995, unless otherwise noted.